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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,100	01/04/2005	Masaya Tanaka	4731-0108PUS1	6992

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EXAMINER	
KASSA, TIGABU	

ART UNIT	PAPER NUMBER
4161	

NOTIFICATION DATE	DELIVERY MODE
05/13/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/520,100	TANAKA, MASAYA	
	Examiner	Art Unit	
	TIGABU KASSA	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/04/2005 and 11/28/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

This application is a 371 of PCT/JP03/08568 filed on 07/04/2003, which is filled at national stage 01/04/2005. Claims 1-12 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Priority

The earliest effective filing date afforded for the instantly claimed invention, has been determined to be 07/04/2003, the filing date of the PCT/JP03/08568.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on January 4, 2005 and November 28, 2007 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim objections

Claims 1-11 are objected due to the recitation of "A material for formation of carbon dioxide external preparation". It is not proper idiomatic English and is awkward.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 12 is rejected under 35 U.S.C. § 102(b) as being anticipated by Tanaka et al. (WO 99/24043; PCT Pub. Date May 20, 1999) using (U.S. patent No. 6,689,339; Issued Feb 10, 2004 as translation of WO 99/24043) and as evidenced by Kenneth N Anderson et al., Mosby's Medical, Nursing, and Allied Health dictionary 1528 (Mosby 5th ed. 1998).

3. Instant claim 12 recites the preparation of carbon dioxide for external use by reacting a composition which contains water, a thickener, and an acid to a carbonate salt.

4. Tanaka et al. (WO 99/24043) discloses " viscous compositions containing carbon dioxide, formed by incorporating carbon dioxide in the form of bubbles in a water-containing viscous composition containing one or more thickener(s)" (column 2, lines 37-41) for mucocutaneous or transmucosal absorption of carbon dioxide. Tanaka et al. also discloses kits for carbon dioxide external use, comprising carbonate salt and a water-containing viscous composition (column 3, lines 40-45). Tanaka et al. ('043) also states that the "carbon dioxide is generated by a reaction between an acid and a carbonate salt (column 3, lines 14-18). Tanaka et al. (WO 99/24043 also discloses that the composition may be applied to a part of the body directly, by impregnating the viscous composition using an absorbent material such as a gauze or sponge (column 11, lines 4-5). "A sponge is defined as a resilient absorbent mass used to absorb fluids, to apply medication, or to cleanse. It may be manufactured from cellulose, rubber, or synthetic material" (Kenneth N. Anderson et al., Mosby's Medical, Nursing, and Allied Health dictionary 1528 (Mosby 5th ed. 1998)). Thus, the sponge of Tanaka et al would

necessarily be a polymeric three-dimensional network structure as recited. Furthermore, since carbon dioxide is somewhat soluble in aqueous solutions, the product of Tanaka et al. would inherently include at least some carbon dioxide in a non-bubble state, thus meeting the limitation of instant claim 12. According to the recitation in instant claim 12, since the reaction has already occurred before impregnation to the polymeric three-dimensional network structure Tanaka et al. (WO 99/24043) reads on claim 12.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

4. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (WO 99/24043; PCT Pub. Date May 20, 1999) using (U.S. patent No. 6,689,339; Issued Feb 10, 2004 as translation of WO 99/24043) in view of Gibbins et al. (WO 01/49258 PCT Pub. Date July 12, 2001)

5. Instant claim 1 recites a material for formation of carbon dioxide external preparation, characterized by comprising: a base agent that comprises a polymeric three-dimensional network structure impregnated with a viscous material containing at least an acid and water, and is made to contact with the skin in use; and a reactant that contains at least a carbonate, and is made to contact with the base agent in use so as to generate carbon dioxide, the carbon dioxide dissolving in the viscous material substantially in a non-bubble state.

6. Tanaka et al discloses a material for formation of a carbon dioxide external preparation that includes a viscous material containing at least an acid and water (column 3, lines 39-40) and a reactant that contains carbonate (column 3, lines 39). Prior to use, the carbonate is reacted with the viscous material which produces a carbon dioxide containing product and the product is contacted with skin using a gauze or

sponge that is impregnated with the product (column 11, lines 4-6). This differs from the material claimed in that the viscous material is not initially impregnated in a polymeric three-dimensional network structure prior to reacting it with the carbonate, as recited.

7. However Gibbins et al. discloses matrices such as polyacrylamide and a non-gellable mucopolysaccharide, which are polymeric three-dimensional network structures, being used to trap a gas generated after a reaction between two different reactants (page 18, lines 7-11). Gibbins et al. (WO 01/49258) discloses that the gas bubbles are generated by the permeation of the second reactant added to the formed matrix that contains the first reactant (page 18, lines 13-14). The reaction between the two reactants *in situ* results in the liberation of gas which is entrapped within the matrix (page 18, lines 14-16). Gibbins et al. (WO 01/49258) also discloses the possibility of incorporating an active agent with the second reactant, which is similar to the viscous composition in the instant application (page 18, lines 10-11). Gibbins et al. (WO 01/49258) also mentions that the composition can be added to the preformed matrix either simultaneously or sequentially, for perfusion within the matrix (page 21, lines 20-23). The formed matrix is then placed in the presence of the second reactant for the reaction to proceed so as to form the gas bubbles (page 18, lines 14-16). Gibbins et al. (WO 01/49258) also specifically discloses the possibility of generating of carbon dioxide gas within the matrix by reacting an acid catalyst (which is similar to the viscous composition containing acid in the instant application) which is incorporated in the matrix followed by the perfusion of the matrix with a carbonate (page 15, lines 10-12).

8. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to impregnate the viscous composition of Tanaka into a sponge prior to reacting it with carbonate salt as an alternative to impregnation of the viscous composition for the liberation of carbon dioxide for external use into the sponge after reacting the viscous composition containing an acid with the carbonate salt. A reason for doing this is to eliminate the mixing prior to the impregnating, as suggested by Gibbins.

9. Instant claims 2-3, 6, and 10 recite about different features of the polymeric three-dimensional network structure being sheet-like, a fibrous or porous absorbent, and a non woven cloth or a sponge. As per the disclosure by Tanaka et al. for the possibility of impregnating the viscous composition using an absorbent material such as a gauze or sponge or by patching a bag made of the absorbent material wherein the composition is filled (column 11, lines 4-6), a sponge is a polymeric three-dimensional network, which can be sheet-like, fibrous or porous absorbent.

10. Tanaka et al. also discloses a list of thickeners which can be natural polymers, semi-synthetic polymers, or inorganic substances (column 2, lines 42-46). For natural polymers used as a thickener (gum Arabic, carrageenan, galactan……) (column 2, lines 47-55), for the semi-synthetic polymer used as a thickener (ethyl cellulose, carboxymethyl cellulose and salts thereof….) (column 2, lines 55-67 and column 3, lines 1-2), and for synthetic polymer used as a thickener (carboxyvinyl polymer, sodium polyacrylate, polyvinylacetaldiethylaminoacetate, polyvinyl alcohol, polyvinyl pyrrolidone….). Thus, Tanaka et al. read on claims 4, 6, 8, and 9 in the instant

application. Furthermore, Tanaka et al. also mentions a list of acids that can be used for the generation of carbon dioxide (formic acid, acetic acid, propionic acid, butyric acid, valeric acid, oxalic acid, malonic acid, succinic acid, glutaric acid….)(column 3, lines 19-34), and also a list of carbonates ammonium carbonate, potassium carbonate, calcium carbonate, sodium carbonate, sodium bicarbonate, potassium bicarbonate, potassium sesquicarbonate…) (column 3, lines 35-38), which reads on claims 6 and 9 in the instant application.

11. With regard to claim 5 in the instant application, Tanaka et al. teaches that the viscous composition containing at least an acid, water, an oil or and a surfactant can be applied for treating the mucocutaneous or injured tissue, hair, etc in the form of gel, cream, paste, mousse or the like (column 6, lines 37-39).

12. Instant claim 7 recites wherein the reactant is a viscous material further containing a thickener and water. Tanaka et al. discloses a kit containing an aqueous viscous composition comprising a carbonate or carbonates, an acid or acids, a thickener or thickeners and water (column 4, lines 4-6).

13. With respect to instant claim 10 Tanaka et al. discloses a kit comprising an acid – containing aqueous viscous composition and carbonate-containing sheet (column 6, lines 60-61). Additionally, Tanaka et.al. also discloses that the part of the body to which the composition is applied is covered with a film of poor permeability or dressing material (column 11, lines 9-11) , which reads on claim 11 of the instant application.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu kassa 05/06/2008

TK

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161